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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,769	01/30/2004	Nicholas V. Perricone	00961-P0146C	7069

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,769	PERRICONE, NICHOLAS V.	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 1/30/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively obvious over Cole (US6444195) , Watson (US6482446) or Shapiro(US 6372791), alone.

The claims are drawn to a method of treating acne using a topical composition comprising an alkanolamine(e.g. dimethylaminoethanol, in an amount about 0.1-10%), tyrosine(0.01-6%), a sulfur-containing ingredient (e.g. lipoic acid or glutathione or mixtures thereof, 0.01-10%), or optionally salicylic acid, retinoids, ascorbic acid, etc.

Firstly, Cole(US'195, hereinafter) teaches a topical composition used in the treatment of various skin disorders such as dermatoses and erythemas, skin cancer, or

skin aging and so on. US'195 further teaches the acne/wrinkle treating agents as additional active agents which are beneficially incorporated into the patented composition to enhance the therapeutic effectiveness, wherein said active agents are comprising alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives, retinoic acid, salicylic acid, and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 5, line 3 and lines 14-34 and claims 17. Therefore, the claimed feature are inherently met where the topical application is applied, the acne will be treated naturally since acne treating active agents are added into the patented composition as set forth above.

Thus, all the critical elements required by the instant claims are well taught and the claims are anticipated by the cited reference.

Secondly, Watson(US446) or Shapiro et al(US'791) also teaches a treatment of various skin conditions using a topical composition comprising all the ingredients required by the instant claims as well.

For example, US'446 teaches improving skin conditions and treating undesriable skin conditions using topical composition comprising salicylic acid as an actibe agent and additionally alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 3, line 65 and col. 3, lines 1-22.

US'791 also teaches a treatment for unwanted skin conditions using a topical composition comprising an alkanolamine(e.g. dimethylaminoethanol), lipoic acid,

tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 4, lines 17-43.

Even if the claimed composition may not be included in the examples, and the weight amounts for these ingredients are not individually taught, it would have been readily apparent to any skilled artisan how to make the composition comprising such ingredients with titrating effective dosage for each active agent to maximize the therapeutic effectiveness within the given teaching(0.001-20%). One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these patents cited. In order to determine best outcome, the variations including dosage regimens(e.g. interval(e.g. sequential or concurrent administration), frequency, variations in formulations or routes of administration are easily modified and considered to be minor, which does not render the claimed invention patentably distinct because the techniques and skills are routinely practiced and well known in the industry and well within the skill level of the skilled artisan.

Thus, the claims are not patentably distinct over the prior art of the record.

3. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively obvious over Perricone (US 6743433, 6365623).

Because patented invention relates to a method of treating acne using the substantially same composition, the claimed invention is not patentably distinct.

For example, US'433 teaches all the critical elements(see claims) and US'623 also teaches acne treatment and the composition comprising all the ingredients required by the claims, see abstract and column 10, lines 42-50.

The claimed invention(US'623) also utilizes the composition comprising alknolamine derivatives(1-10%) such as esters of diethylaminoethanol, tyrosine(2-5%), lipoic acid(0.25-5%) , hydroxyl acid(e.g. glycolic acid, 3-7%), ascorbic acid derivatives(1-7%), salicylic acid, retinoids, etc for the treating acne and the instant claims also relates to an ane treatment using same topical composition (sequentially) requires all the said ingredients(as active agents) taught by both patents , see abstract and claims.

Thus, the scope of claimed invention of instant claims are encompassed by and thus, are not patentably distinct over the prior art of the record.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of US patent No. 6743433. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims(now allowed) of '433 patent are drawn to a method of treating acne comprising firstly applying a composition comprising an effective amount of an alkanolamine(e.g. dimethylaminoethanol), tyrosine, a sulfur containing ingredient such as lipoic acid, or gluthathione) then applying the conventional acne medication such as salicylic acid, retinoic acid, benzoyl peroxide, etc. The scope of claimed invention in both patent ('433) and instant application are overlapping and not patentably distinct over one to the other.

6. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-11 of U.S. Patent No. 6365623. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention(US'623, see abstract and claims) utilizes substantially same composition in the acne treatment, wherein said composition compres alknolamine derivatives(1-10%) such as esters of diethylaminoethanol, tyrosine(2-5%), lipoic acid(0.25-5%) , hydroxyl acid(e.g. glycolic

acid, 3-7%), ascorbic acid derivatives(1-7%), and thus, the scope of claimed invention and patented invention are overlapping and not patentably distinct over one to the other.

Again, the variations including dosage regimens(e.g. interval(e.g. sequential or concurrent administration), frequency, variations in formulations or routes of administration are considered to be minor, which does not render the claimed invention patentably distinct because the techniques and skills are routinely practiced and well known in the industry and well within the skill level of the skilled artisan.

Conclusion

1. No claim is allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
March 21, 2005
Art unit 1614